III (a substance which acts with the anticoagulant heparin to prevent coagulation). This determination is used to monitor the administration of heparin in the treatment of thrombosis. The determination may also be used in the diagnosis of thrombophilia (a congenital deficiency of antithrombin III).

(b) *Classification.* Class II (performance standards).

[45 FR 60609, Sept. 12, 1980]

§ 864.7100 Red blood cell enzyme assay.

(a) *Identification.* Red blood cell enzyme assay is a device used to measure the activity in red blood cells of clinically important enzymatic reactions and their products, such as pyruvate kinase or 2,3-diphosphoglycerate. A red blood cell enzyme assay is used to determine the enzyme defects responsible for a patient's hereditary hemolytic anemia.

(b) *Classification.* Class II (performance standards).

[45 FR 60610, Sept. 12, 1980]

§ 864.7140 Activated whole blood clotting time tests.

(a) *Identification.* An activated whole blood clotting time tests is a device, used to monitor heparin therapy for the treatment of venous thrombosis or pulmonary embolism by measuring the coagulation time of whole blood.

(b) *Classification.* Class II (performance standards).

[45 FR 60611, Sept. 12, 1980]

§ 864.7250 Erythropoietin assay.

(a) *Identification.* A erythropoietin assay is a device that measures the concentration of erythropoietin (an enzyme that regulates the production of red blood cells) in serum or urine. This assay provides diagnostic information for the evaluation of erythrocytosis (increased total red cell mass) and anemia.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 864.3.

[45 FR 60612, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987]

§ 864.7275 Euglobulin lysis time tests.

(a) *Identification.* A euglobulin lysis time test is a device that measures the length of time required for the lysis (dissolution) of a clot formed from fibrinogen in the euglobulin fraction (that fraction of the plasma responsible for the formation of plasmin, a clot lysing enzyme). This test evaluates natural fibrinolysis (destruction of a blood clot after bleeding has been arrested). The test also will detect accelerated fibrinolysis.

(b) *Classification.* Class II (performance standards).

[45 FR 60612, Sept. 12, 1980]

§ 864.7290 Factor deficiency test.

(a) *Identification.* A factor deficiency test is a device used to diagnose specific coagulation defects, to monitor certain types of therapy, to detect coagulation inhibitors, and to detect a carrier state (a person carrying both a recessive gene for a coagulation factor deficiency such as hemophilia and the corresponding normal gene).

(b) *Classification.* Class II (performance standards).

[45 FR 60613, Sept. 12, 1980]

§ 864.7300 Fibrin monomer paracoagulation test.

(a) *Identification.* A fibrin monomer paracoagulation test is a device used to detect fibrin monomer in the diagnosis of disseminated intravascular coagulation (nonlocalized clotting within a blood vessel) or in the differential diagnosis between disseminated intravascular coagulation and primary fibrinolysis (dissolution of the fibrin in a blood clot).

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 864.3.

[45 FR 60614, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987]